DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

12 MAY 2017

MEMORANDUM FOR SGOED
ATTN: CAPT JOHN HUNNINGHAKE

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **Adjustment of the Severity of Obstruction in Patients with Mixed Obstructive-Restrictive Pulmonary Function Testing** presented at/published to **2017 American Thoracic Society Annual Meeting, Washington DC, 19-24 May 2017** in accordance with MDWI 41-108, has been approved and assigned local file #**17227.**

2. Pertinent biographic information (name of author(s) title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.

3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are a 59 MDW staff member, we can forward your request for funds to the designated Wing POC at the Chief Scientist's Office, Ms. Alice Houy, office phone: 210-292-8029; email address: alice.houy.civ@mail.mil.

4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

for Jane Barnett
LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING

1. The author must complete page two of this form:
   a. In Section 2, add the funding source for your study [e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (8G5 O&M); 8G5 R&D; Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH; Congressionally Directed Medical Research Program (CDMRP) ; Grants; etc.]

   b. In Section 2, there may be funding available for journal costs, if your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.

2. Print your name, rank/grade, sign and date the form in the author's signature block or use an electronic signature.

3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.

4. Attach a copy of your abstract, paper, poster and other supporting documentation.

5. Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.

6. On page 2, have either your unit commander, program director or immediate supervisor:
   a. Print their name, rank/grade, title; sign and date the form in the approving authority's signature block or use an electronic signature.

7. Submit your completed form and all supporting documentation to the CRD for processing (59crdpubspres@us.af.mil). **This should be accomplished no later than 30 days before final clearance is required to publish/present your materials.** If you have any questions or concerns, please contact the 59 CRD/Publications and Presentations Section at 292-7141 for assistance.

8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.

9. Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. **Note:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.

10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/CC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DITC). See 59 MDWI 41-108, *Presentation and Publication of Medical and Technical Papers*, for additional information.

11. The Joint Ethics Regulation (JER) DoD 5500.07-R, *Standards of Conduct*, provides standards of ethical conduct for all DoD personnel and their interactions with other non-DoD entities, organizations, societies, conferences, etc. Part of the Form 3039 review and approval process includes a legal ethics review to address any potential conflicts related to DoD personnel participating in non-DoD sponsored conferences, professional meetings, publication/presentation disclosures to domestic and foreign audiences, DoD personnel accepting non-DoD contributions, awards, honoraria, gifts, etc. The specific circumstances for your presentation will determine whether a legal review is necessary. **If you (as the author) or your supervisor check "NO" in block 17 of the Form 3039, your research or technical documents will not be forwarded to the 502 ISG/JAC legal office for an ethics review.** To assist you in making this decision about whether to request a legal review, the following examples are provided as a guideline:

    For presentations before professional societies and like organizations, the 59 MDW Public Affairs Office (PAO) will provide the needed review to ensure proper disclaimers are included and the subject matter of the presentation does not create any cause for DoD concern.

    If the sponsor of a conference or meeting is a DoD entity, an ethics review of your presentation is not required, since the DoD entity is responsible to obtain all approvals for the event.

    If the sponsor of a conference or meeting is a non-DoD commercial entity or an entity seeking to do business with the government, then your presentation should have an ethics review.

    If your travel is being paid for (in whole or in part) by a non-Federal entity (someone other than the government), a legal ethics review is needed. These requests for legal review should come through the 59 MDW Gifts and Grants Office to 502 ISG/JAC.

    If you are receiving an honorarium or payment for speaking, a legal ethics review is required.

    If you (as the author) or your supervisor check "YES" in block 17 of the Form 3039, your research or technical documents will be forwarded simultaneously to the 502 ISG/JAC legal office and PAO for review to help reduce turn-around time. If you have any questions regarding legal reviews, please contact the legal office at (210) 671-5795/3365, DSN 473.

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:
"The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components"

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving humans:
"The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN 40-401_IP :
"The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol)	3. GME/GHSE STUDENT:	4. PROTOCOL NUMBER:
	John Hunninghake, O-3, MC, 959 CSPS	☒ YES ☐ NO	C.2016.102d

5. PROTOCOL TITLE: (NOTE: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.)
Interpretation of Mixed Obstructive-Restrictive Pulmonary Function Testing

6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED:
Adjustment of the Severity of Obstruction in Patients with Mixed Obstructive-Restrictive Pulmonary Function Testing

7. FUNDING RECEIVED FOR THIS STUDY? ☐ YES ☒ NO FUNDING SOURCE:

8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: ☐ YES ☒ NO

9. IS THIS MATERIAL CLASSIFIED? ☐ YES ☒ NO

10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.?
☐ YES ☒ NO NOTE: If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.

11. MATERIAL IS FOR: ☒ DOMESTIC RELEASE ☐ FOREIGN RELEASE
CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED.

☐ 11a. PUBLICATION/JOURNAL (List intended publication/journal.)

☐ 11b. PUBLISHED ABSTRACT (List intended journal.)

☐ 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)

☒ 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meting.)
2017 American Thoracic Society Annual Meeting, Washington, DC, 19-24 May 2017

☐ 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.)

12. HAVE YOUR ATTACHED RESEARCH/TECHNICAL MATERIALS BEEN PREVIOUSLY APPROVED TO BE PUBLISHED/PRESENTED?
☐ YES ☒ NO ASSIGNED FILE # _____ DATE _____

13. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC
NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC).

DATE
May 01, 2017

14. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email)	15. DUTY PHONE/PAGER NUMBER
Hunninghake, John, C, john.c.hunninghake.mil@mail.mil	210-513-7605

16. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.

LAST NAME, FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (If not 59 MDW)
a. Primary/Corresponding Author Hunninghake, John C	0-3	959 CSPS	
b. Skabelund, Andrew J	0-4	59 MDSP/SGMSP	
c. Hull, James	0-4	59 MDSP/SGMSP	
d. Morris, Michael	CIVILIAN	CIVILIAN	SAMMC
e.			

17. IS A 502 IRB/JAC ETHICS REVIEW REQUIRED (JER DOD 5500.07-R)? ☐ YES ☒ NO

I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401_IP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.

18. AUTHOR'S PRINTED NAME, RANK, GRADE	19. AUTHOR'S SIGNATURE	20. DATE
John Hunninghake, 0-3, MC	HUNNINGHAKE.JOHN.C.1368152108	April 05, 2017
21. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE	**22. APPROVING AUTHORITY'S SIGNATURE**	**23. DATE**
Ed McCann, 0-4, MC, Pulmonary Fellowship Program Director	MCCANN.EDWARD.T.1244108845	April 19, 2017

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1st ENDORSEMENT (59 MDW/SGVU Use Only)

TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.	24. DATE RECEIVED May 02, 2017	25. ASSIGNED PROCESSING REQUEST FILE NUMBER 17227
26. DATE REVIEWED 12 May 2017		27. DATE FORWARDED TO 502 ISG/JAC

28. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: ☒ NO ☐ YES If yes, give date. _____ ☐ N/A

29. COMMENTS ☒ APPROVED ☐ DISAPPROVED

The abstract is approved.

30. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	31. REVIEWER SIGNATURE	32. DATE
Rocky Calcote, PhD, Clinical Research Administrator	CALCOTE.ROCKY.D.1178246844	

2nd ENDORSEMENT (502 ISG/JAC Use Only)

33. DATE RECEIVED	34. DATE FORWARDED TO 59 MDW/PA

35. COMMENTS ☐ APPROVED (In compliance with security and policy review directives.) ☐ DISAPPROVED

36. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	37. REVIEWER SIGNATURE	38. DATE

3rd ENDORSEMENT (59 MDW/PA Use Only)

39. DATE RECEIVED	40. DATE FORWARDED TO 59 MDW/SGVU
May 12, 2017	May 12, 2017

41. COMMENTS ☒ APPROVED (In compliance with security and policy review directives.) ☐ DISAPPROVED

42. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	43. REVIEWER SIGNATURE	44. DATE
Kevin Iinuma, SSgt/E-5, 59 MDW Public Affairs		May 12, 2017

4th ENDORSEMENT (59 MDW/SGVU Use Only)

45. DATE RECEIVED	46. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL ☐ YES ☐ NO ☐ COULD NOT BE REACHED ☐ LEFT MESSAGE

47. COMMENTS ☐ APPROVED ☐ DISAPPROVED

48. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	49. REVIEWER SIGNATURE	50. DATE

Adjustment of the Severity of Obstruction in Patients with Mixed Obstructive-Restrictive Pulmonary Function Testing

Hunninghake JH, Skabelund AJ, Hull JE, Morris MJ

RATIONALE:
The interpretation of a pulmonary function test (PFT) can be challenging in patients with mixed obstructive and restrictive disorders, especially in regards to the degree of obstruction. Prior studies identified the FEV1 overestimates the degree of obstruction because FEV1 is reduced from both the obstructive and restrictive components of the underlying disease. One smaller study adjusted the FEV1 for the decrease in TLC to better define the severity of underlying airway obstruction, which resulted in 83% of patients being changed to a less severe grade of obstruction according to ATS/ERS guidelines. This study aims to evaluate a larger population of patients with a mixed obstructive-restrictive pattern on full PFTs in order to correlate the grade of obstruction based on the degree of restriction and underlying lung disease.

METHODS:
This study is a retrospective chart review of the PFT databases from multiple institutions. We selected individuals with both obstructive (FEV1/FVC < lower limit of normal) and restrictive (TLC <80%) lung disease. The severity of obstruction for unadjusted (FEV1 % predicted alone) versus adjusted (FEV1 % predicted / TLC % predicted) values were compared and reported according to ATS/ERS guidelines. Additional comparisons were made based on the degree of restriction (< 70% vs. < 80%) and cause of underlying lung disease (COPD vs. other obstructive diseases).

RESULTS:
A large PFT database was evaluated, which yielded 401 individual patients who satisfied our study inclusion criteria. By unadjusted FEV1, a total of 43% patients were categorized as having severe or very severe obstruction, 47% with moderate to moderately severe obstruction, and 10% with mild obstruction. After adjustment for FEV1%/TLC%, 96% of patients were reclassified to a lesser degree of obstruction. After adjustment, 7% patients were reclassified as severe or very severe obstruction, 26% with moderate to moderately severe obstruction, and 67% with mild or no obstruction. In a comparison of patients with TLC <70% vs. <80%, 99% of those 184 patients with a TLC <70% were reclassified. With regards to diagnosis, 99% of COPD patients were reclassified to a lesser degree of obstruction vs. 90% of non-COPD patients that were reclassified.

CONCLUSIONS:
Adjusting the method to grade obstruction in patients with combined obstructive and restrictive disorders resulted in a significant reclassification of obstruction to a lesser degree, especially in patients with COPD and a more severe restrictive process. Clinical correlation with the degree of impairment is ongoing.

DEPARTMENT OF THE ARMY
REGIONAL HEALTH COMMAND CENTRAL (PROVISIONAL)
4070 STANLEY ROAD, SUITE 121
JBSA FORT SAM HOUSTON, TEXAS 78234-2715

REPLY TO ATTENTION OF

MCSR-CS

April 25, 2016

MEMORANDUM FOR: Michael Morris, MD
FROM: Brooke Army Medical Center Institutional Review Board

PROJECT TITLE: Interpretation of Mixed Obstructive-Restrictive Pulmonary Function Testing
REFERENCE #: C.2016.102d
SUBMISSION TYPE: NEW PROJECT

ACTION: APPROVED
APPROVAL DATE: April 25, 2016
EXPIRATION DATE: April 25, 2017
REVIEW TYPE: EXPEDITED

1. Congratulations! The Brooke Army Medical Center (BAMC) Institutional Review Board (IRB) reviewed and APPROVED your aforementioned protocol and supporting documents. The research is judged to constitute minimal risk. The protocol has been assigned control number C.2016.102d. Please refer to this designation in all correspondence. Your protocol was reviewed for regulatory compliance under the expedited review, in accordance with 32CFR219.110 (b) Federal Register Category (5). Applicable OHRP (under 45CFR46), FDA (under 21CFR50 and 56) and HIPAA (45CFR160 and 164) regulations were also consulted, as appropriate.

2. As part of this approval, the following determinations were made:

a. The protocol, P03, Version #1, Dated 25 April 2016, is approved to review medical records of all patients (ages 18-89) who have completed a full pulmonary function test (spirometry, lung volumes and diffusing capacity), evaluated at San Antonio Military Medical Center and Wilford Hall Ambulatory Surgical Center from 1 January 2009 to 31 December 2015.

b. A waiver of informed consent has been approved IAW 32 CFR219.116(d) for the entire study.

c. A HIPAA waiver has been submitted and approved.

d. No funding is requested from the BAMC Department of Clinical Investigation.

3. A Research Monitor is not required; protocol is no greater than minimal risk.

4. You are required to report all unanticipated problems involving risks to subjects or others (UPIRSOs) and Serious Adverse Events (SAEs) to the IRB. Any unanticipated adverse events

must be reported to the Human Protection Administrator within 48-hours by phone at (210) 916-2598 or (210) 916-0606 or by email at usarmy.ibsa.medcom-bamc.mbx.bamc-irb@mail.mil

5. This protocol will automatically expire on 25 April 2017. If you plan to continue beyond this date, the required continuing review progress report is due to the BAMC IRB no later than six (6) weeks prior to expiration. The IRB will attempt to assist you by sending a reminder; however, submission of the continuing review report is your responsibility. Failure to submit the report on time will result in the expiration of your protocol and a requirement to cease all research activities until the entire protocol can be resubmitted.

6. Please be sure to maintain all records in accordance with the terms set forth in your protocol. You are required to have all records, including informed consent and HIPAA documents, available for review by the IRB or other federal agencies.

7. Any changes to your protocol, including any changes in personnel, may not be made without prior IRB approval. Please forward a request for any changes, along with their rationale to the BAMC IRB for review and approval.

8. Please inform the IRB when the protocol is completed or changes status and forward any significant findings.

9. Abstract and/or manuscript submissions resulting from this research should be cleared IAW local publication clearance policies.

10. If at any time you have questions regarding your responsibilities as a Principal Investigator, please contact the IRB office at 210-916-7837. On behalf of the entire IRB, we wish you much success with your research protocol. We look forward to reviewing the progress of your study in the coming months.

PLATTEBORZE.LYNN.SHEFFLER.1250697933

Digitally signed by PLATTEBORZE.LYNN.SHEFFLER.1250697933
DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USA, cn=PLATTEBORZE.LYNN.SHEFFLER.1250697933
Date: 2016.04.25 11:03:31 -05'00'

Lynn S. Platteborze
MS, RAC, CIP
Designated Expedited Review IRB Member

4. If at any time you have questions regarding your responsibilities as a Principal Investigator, please contact the undersigned at (210) 916-9425 or dustin.m.thomas4.mil@mail.mil On behalf of the entire IRB, we wish you continued success with your research protocol. We look forward to reviewing the progress of your study in the coming months.

DUSTIN M. THOMAS
MAJ, MC, USA
Designated Expedited Review Member